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Willimastown, MA 01267

EXAMINER
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WRIGHT, PATRICIA KATHRYN

ART UNIT	PAPER NUMBER
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1797

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/769,017	<b>Applicant(s)</b> TANAAMI, TAKEO	
	<b>Examiner</b> P. Kathryn Wright	<b>Art Unit</b> 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 April 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 32-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 32-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Status of the Claims***

1. This action is in response to papers filed April 10, 2008 in which claims 1-6, 22 and 32 were canceled and claims 33-38 were added. The amendments have been thoroughly reviewed and entered.

Applicant's arguments have been thoroughly reviewed but are deemed moot in view of the amendments, withdrawn rejections and new grounds for rejection. Any objection/rejection not repeated herein has been withdrawn by the Office.

New grounds for rejection, necessitated by the amendments, are discussed.

Claims 32-38 are under prosecution.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 32-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 33 recites "said biochip" in the preamble. There is no antecedent basis for this limitation in the claim. Claim 33 also refers to "different locations". What "locations" is Applicant referring to?

Claim 34 recites wherein the spectroscopic information is develop in a two dimensional manner when the plurality of samples are arranged in spots on the biochip

surface. Claim 36 recites wherein the spectroscopic information is separated from noise. The claims are directed to an apparatus (i.e., biochip reader). No structural elements are recited in these claims only methods of processing the spectroscopic information. Moreover, there is no means for performing these methods. Applicant is reminded that only structural language is determinative of the metes and bounds of an apparatus claim, not method steps. Also note that claim 34 recites the conditional phrase, "when said plurality of samples are arranged in spots on said biochip surface". This does not require that the plurality of samples be arranged in spots on the biochip surface.

Claims 34 and 38 are drawn to the biochip. These recitations are indefinite because it cannot be clearly determined if the biochip has been positively recited as part of the claimed device. For the purposes of examination, the recitation of the biochip has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the structural limitations to the biochip reader are able to stand alone.

Claim 35 recites "a microscope". This claim is confusing and indefinite since it omits the essential structural cooperative relationships of elements, amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: the "microscope" and the other elements of the invention (i.e., light source, optical detector).

The claims not appear to positively recite the biochip as a claimed element of the biochip reader. Therefore, claim 38 fails to further limit the parent claim.

Clarification and/or correction is required.

### ***Claim Objections***

4. Claim 36 is objected to because of the following informalities: "noice" should be changed to --noise--. Appropriate correction is required.
5. Claim 38 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. See reasons delineated above.

### ***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 33-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Ogino (US Patent no. 5,422,712).

Ogino discloses a biochip reader for measuring binding affinity of samples which comprises a confocal microscope configuration communicating with a sample biochip (flow cell 16) through an objective lens 14 (see for example, Fig. 1).

Specifically, Ogino teaches a biochip reader comprising a light source 10 for exciting a plurality of samples (cells) in the flow cell and causing the cells to emit fluorescent light different in wavelength from the excitation light (see col. 3, lines 6-7).

The Ogino biochip reader includes an optical detector 34, 70.

Ogino also teaches a means comprising a dichromatic mirror 24. The mirror meets the limitation of the "means" in claim 33. However, note that Ogino also teaches a spectroscopic means 28 comprising a prism, a lattice (grating) disposed between the sample and the optical detector 34 which causes the fluorescent light emitted by the samples to be separated and developed by a processor 38 as spectroscopic information at different locations (different cells) according to wavelength and detected by the optical detector at the different locations (i.e., different cells).

Regarding claim 34, Ogino also teaches a processor 38 for developing the spectroscopic information. Note that claim 34 recites the conditional phrase, "when said plurality of samples are arranged in spots on said biochip surface". This claim construction makes optional the plurality of samples on the biochip surface and therefore, Ogino need not teach the plurality of samples be arranged in spots on the biochip surface.

As to claim 36, the biochip reader of Ogino also includes an image intensifier 30 which separates the spectroscopic information from noise using spectra and regression method.

Regarding claim 37, Ogino teaches a slit or aperture 68 (see col. 8, lines 53 et seq. and Fig. 10)

Please note, that the plurality of sample arranged in spots or arrays on a biochip are not positively recited in the claims. Moreover, even if the plurality of samples are positively recited in the claim it would not serve to patentably distinguish the device since the inclusion of material worked upon by a structure being claimed is of no significance in determining patentability of an apparatus claim. See MPEP 2115.

Instant claim 38 is inherently anticipated by Ogino because it fails to further limit parent claim 33.

8. Claims 33-38 are rejected under 35 U.S.C. 102(e) as being anticipated by Kauvar et al. (US Patent no. 6,492,125), hereinafter "Kauvar".

Kauvar discloses a biochip reader for measuring binding affinity of samples which comprises a confocal microscope communicating with a sample biochip through an objective lens (Fig. 1).

Specifically, Kauvar teaches a biochip reader comprising a means which comprises a polychromatic mirror (i.e., dichromatic mirror), see Fig. 1. Note that Kauvar also teaches a grating and Fourier spectrometer (see col. 8, lines 20 et seq.) Thus, a single detector may be employed using appropriate filters or other means, such as a

prism or grating, to permit a single detector to perceive separately multiple signals, such as different wavelength ranges, see for example, col. 2, line 54 et seq.

As to claim 34, Kauvar also teaches a computer for developing the spectroscopic information in a two dimensional manner.

With respect to claim 35, the apparatus depicted by Kauvar in Figure 1 comprises a scanning confocal microscope for fluorescence measurements.

Regarding claims 36-37, the biochip reader of Kauvar separates the spectroscopic information from noise using known spectra and regression method and an aperture (see col. 8, lines 20 et seq.)

Please note, that the sample is not positively recited in the claims. Moreover, even if the plurality of samples arranged in an array are positively recited in the claim it would not serve to patentably distinguish the device since the inclusion of material worked upon by a structure being claimed is of no significance in determining patentability of an apparatus claim. See MPEP 2115.

Instant claim 38 is inherently anticipated by Kauvar because it fails to further limit parent claim 33. Nevertheless, Kauvar teaches a biochip formed from a transparent substrate to allow passage of the excitation light and the fluorescent light, wherein the excitation light is irradiated from the bottom side of the biochip opposite the top side on which the plurality of samples are disposed (see Fig. 1.)



***Response to Arguments***

9. Applicant's arguments filed April 10, 2008 have been fully considered but they are not persuasive.

In response to the previous rejection of claims 1-6, 22 and 32 under 35 U.S.C. 102(b) as being anticipated by Ogino (US Patent no. 5,422,712), Applicant argues that Ogino reads "particles" such as blood and urine contained in a "sample liquid flow", not "a plurality of biological samples provided as spots or an array on a surface of a biochip".

The Examiner respectfully disagrees. It is noted that the recitation biochip and samples thereon has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

In response to the previous rejection of claims 1-5, 22, and 32 under 35 U.S.C. 102(e) as being anticipated by Kauvar (US Patent no. 6,492,125), Applicant argues that Fig.1 does not show any grating, dichromic mirror, or Fourier spectrometer to spit the sample into emitted fluorescent light. Applicant argues that the device of Kauvar utilizes "emission" filter, "shutters", and "emission filter wheels" and "an

excitation filter wheel". From this Applicant broadly asserts that the disclosure of Kauvar is different from the instant invention.

The Examiner respectfully disagrees with Applicant's arguments. Kauvar teaches a biochip reader comprising a means having a polychroic mirror (i.e., dichromatic mirror), see Fig. 1. In addition, Kauvar teaches a grating and Fourier spectrometer which splits the sample emitted fluorescent light (see col. 8, lines 20 et seq.) Also, the fact that Kauvar employs other elements not required by Applicant's invention is not germane since Kauvar does teach all the essential elements set forth in the claims. The open ended "comprising language" of the claims means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim. See MPEP 2111.03.

Therefore, for the reasons set forth above, all pending claims remain rejected.

### ***Conclusion***

10. No claims are allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Kathryn Wright whose telephone number is 571-272-2374. The examiner can normally be reached on Monday thru Thursday, 9 AM to 6 PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

pkw

/Jill Warden/  
Supervisory Patent Examiner, Art Unit 1797